DEC 2 1 2012

Summary of Safety and Effectiveness

Date: May 22, 2012

Manufacturer:
Limacorporate S.p.A.
Via Nazionale, 52
33038 – Villanova di San Daniele
Udine - Italy

U.S. Contact Person:
Cheryl Hastings
Principal Consultant
Phone: 574-527-4220

Product	Product Code	Regulation and Classification Name
Delta TT Acetabular System	LPH, MBL	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3358

Description:

The Delta TT Acetabular System consists of a Delta TT cup, a liner and a modular metal femoral head. Bone screws can also be used to give further stability to the cup.

The Delta TT cup is manufactured using an EBM (Electron Beam Melting) process with titanium alloy powder (Ti6Al4V, ASTM F1472 – ISO 5832-3). The Delta TT cup consists of a non porous bulk interior surface and a Trabecular Titanium structure on the external surface.

The Delta TT cup has an external hemi-spherical shape. A polar threaded hole is used for introduction of the cup and mates with the polar peg of the liner when the two components are assembled. Three threaded holes in lateral positions allow additional fixation of the cup using bone screws (polyethylene plugs are used when bone screws are not required). The Delta TT cup is designed to be coupled with ultra high molecular weight polyethylene (UHMWPE) liners by means of a taper coupling.
Delta TT cups are available with external diameters of 44, 46 and 48 mm (for Small liners), 50 and 52 mm (for Medium liners) and 54, 56, 58, 60, 62 and 64 mm (for Large liners).

The liners for Delta TT cups are manufactured from standard UHMWPE (ASTM F648 – ISO 5834-2) or from cross-linked UHMWPE (X-Lima).
Liners are coupled with the Delta TT cup by means of a taper coupling. Two features are intended to give stability to the coupling. A peripheral ring manufactured from Ti6Al4V (ASTM F1472 – ISO 5832-3) surrounds the taper of the liner circumferentially, enhancing the rotational stability of the coupling. A polar peg fits into the polar hole of the cup, increasing the lever-out stability of the liner. The top of the peg is resurfaced by a Ti6Al4V (ASTM F1472 – ISO 5832-3) plug to avoid direct contact between polyethylene and bone.

Liners are available in two versions: neutral and protruded. The protruded design provides greater coverage of the femoral head and is intended to reduce the risk of dislocation. For both the designs, the following sizes are available:

- Cross-linked UHMWPE liners: Small (for femoral heads Ø 28 mm), Medium (for femoral heads Ø 28 and 32 mm) and Large (for femoral heads Ø 28, 32 and 36 mm).
- Standard UHMWPE liners: Small, Medium and Large liners for femoral heads Ø 28 mm.

Bone screws are manufactured from Ti6Al4V (ASTM F1472 – ISO 5832-3) and can be used to provide additional initial stability to the cup. Bone screws have a diameter of 6.5 mm and are available in lengths of 20, 25, 30, 35, 40, 45, 50, 55 and 60 mm.

Intended Use/Indications: the Delta TT Acetabular System is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis and hip dysplasia;
- Rheumatoid arthritis;
- Post-traumatic arthritis,
- Correction of functional deformity;
- Fractures, dislocation of the hip and unsuccessful cup arthroplasty;
- Revisions in cases of good remaining bone stock.

The Delta TT cup is intended for cementless use.

Predicate Devices:
Continuum and Trilogy Integrated taper Acetabular systems (Zimmer Inc., K091508);
Regenerex RingLoc + Modular acetabular shell and ArComXL polyethylene liners (Biomet, K070369 / K042051);
Reflection Dual Dimension shell (Smith & Nephew, K960094);
Pinnacle Acetabular System (DePuy, K001534);
Exactech® Novation® Crown Cup® with InteGrip™ Acetabular Shell (Exactech, Inc. K102975);
FMP Cups (Encore Orthopedics Inc, K973119, K974093, K974095, K072154);
CLS Spotorno Expansion Cup / Threaded Acetabular Cup (Zimmer Inc., K850766);
Zimmer Trabecular Metal Modular Acetabular System (Zimmer Inc., K021891);
Trilogy Acetabular System (Zimmer Inc., K953490, K934765);
Alloclassic Zweymuller Cup (Allo Pro Corp., K851213).

Comparable Features to Predicate Device(s): the Delta TT Acetabular system is similar to the predicate devices in terms of intended use, indications, design and materials.
The Delta TT Acetabular system and the predicate acetabular cups are indicated for use in total hip arthroplasty and are intended for uncemented use.

The Delta TT acetabular cup is characterized by an outer hemispherical geometry similar to Zimmer, RingLoc (Biomet) and Pinnacle (DePuy) acetabular cups while the Reflection (Smith & Nephew) cups have a hemispherical shape but are wider in the peripheral region. The purpose of the external porous trabecular titanium structure of the Delta TT cup is the same (to allow biological fixation) as the porous coating of the Trabecular Metal (Zimmer), the Regenerex porous titanium construct (Biomet) and the Reflection (Smith & Nephew) cups. The Pinnacle cups (DePuy) are also externally porous coated.
The EBM manufacturing technique of Delta TT cups is the same as the Exactech® Novation® Crown Cup® with InteGrip™ Acetabular Shell (Exactech, Inc. K102975).

Liners for the Delta TT cups are provided in different designs (neutral and protruded): the same designs are also available for the predicate devices although they are named differently. The coupling between the Delta TT cups and liners is very similar to the Continuum (Zimmer) and Pinnacle (DePuy) systems with a tapered coupling in the peripheral region and a spherical geometry in the polar area.
The components of the Delta TT Acetabular system are manufactured from the same materials as the predicate devices.

Non-Clinical Testing: The Delta TT Acetabular system has undergone bench testing, including deformation, fatigue-fretting of the metal shell and push-out, lever-out and torque-out testing to demonstrate the strength of the cup-liner modular connection. The Delta liners have undergone wear tests. A Range of Motion simulation has been performed to ensure the device design does not overly limit range of motion. The Delta TT cups have undergone two point fatigue testing to failure and were compared with FMP cups tested with the same protocol. The EBM Ti6Al4V has undergone characterization for tensile, yield, elongation and rotating beam fatigue properties and the properties were compared with standard materials used for the manufacturing of predicate acetabular cups. Biocompatibility testing has also been completed. All mechanical testing was done on worst case components or constructs. Where possible, standard test methods were used to allow comparison to testing of the predicate devices. The testing results demonstrated the system's ability to perform under expected clinical conditions.

Clinical Testing: Clinical testing was not necessary to demonstrate substantial equivalence of the Delta TT Acetabular System to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Limacorporate S.p.A.
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December 21, 2012

Re: K112898
Trade/Device Name: Delta TT Acetabular System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, MBL
Dated: December 7, 2012
Received: December 10, 2012

Dear Ms. Hastings:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Unknown

Device Name: Delta TT Acetabular System

Indications for Use:

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Indications for Use

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The Delta TT cup is intended for cementless use.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Krishna Arundi
Division of Orthopedic Devices